

REMARKS

Claims 1, 6, 8 and 10-14 currently appear in this application. The Office Action of May 22, 2006, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 101

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is said to be directed to non-statutory subject matter.

This rejection is respectfully traversed, Claim 1 has been amended in accordance with the Examiner's helpful suggestion to claim a purified anti-allergic royal jelly protein comprising an amino acid sequence of SEQ ID NO:3. Claims 2-5 have been cancelled.

Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process is said to result in an improper definition of a process.

This rejection is respectfully traversed. Claim 6 has been amended to define a method for treating or preventing allergic diseases comprising a step of administering to a patient an effective amount of anti-allergic royal jelly protein, wherein the anti-allergic royal jelly protein comprises the amino acid sequence of SEQ ID NO:1 at the N-terminus and has a molecular weight of about 70 kDa on SDS-PAGE, or comprises the amino acid sequence of SEQ ID NO:2 at the N-terminus and has a molecular weight of about 55 kDa on SDS-PAGE. Support for these amendments can be found in the specification as filed at page 18, lines 8-24 and at pages 22-24, Experiment 3-2 and at pages 24-25, Experiment 3-3. Claim 7 has been cancelled.

Rejections under 35 U.S.C. 112

Claims 1, 2, and 5-13 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that the phrase "where one or more amino acid residues are replaced, inserted, or added in such a manner that the anti-allergic activity of the protein is not substantially eliminated" is indefinite.

This rejection is respectfully traversed. The objected-to phrase has been deleted from claims 1 and 6. Claims 2, 5, 7 and 9 have been cancelled. The remaining claims, 8 and 10-14, depend from amended claim 1 or 6.

The word "substantially" has been deleted from claims 1 and 6 because it was part of the recitation of variants of the claimed sequences. However, it is respectfully submitted that "substantially" is not indefinite. Many Federal Circuit decisions have held that "substantially" is not indefinite. One example is *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 65 USPQ2d 1051 (Fed. Cir. 2002), "Expression s such as 'substantially' are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Such usage may well satisfy the charge to 'particularly point out and distinctly claim' the invention, 35 U.S.C. 112, and indeed may be necessary in order to provide the inventor with the benefit of his invention."

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that because the claims are drawn to an anti-allergic protein which comprises a protein

comprising SEQ ID NOs: 1, 2, 3 or 4 wherein one or more amino acid residues are replaced, inserted or added in such a manner that the anti-allergic activity of the protein is not substantially eliminated is not supported by the specification as filed.

This rejection is respectfully traversed. The claims have been amended to recite a protein which comprises specified amino acid sequences.

Art Rejections

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Katoka et al. Claims 1-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Oka et al. Claims 1-5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al., U.S. 6,165,982.

These rejections are respectfully traversed. None of the cited references discloses or suggests a purified anti-allergic royal jelly protein as defined in claim 1 as amended. None of the cited references discloses or suggests a method for treating or preventing allergic diseases by administering to a patient an effective amount of anti-allergic royal jelly protein as defined in claim 6 as amended.


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In view of the above, it is respectfully submitted
that the claims are now in condition for allowance, and
favorable action thereon is earnestly solicited.

Respectfully submitted,

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